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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,135	06/29/2006	Giampiero de Luca	SER-104	1670

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EXAMINER	
SNYDER, STUART	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,135	DE LUCA, GIAMPIERO	
	Examiner	Art Unit	
	Stuart W. Snyder	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/29/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Cancellation of claims 1-13 in the filing of 10/14/2005 is acknowledged as well as the filing of new claims 14-36 that are subject to examination herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 14-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)).

Nature of the invention: The claims are drawn to a method of treating SARS by administering an IFN to an individual having SARS. Limitations include: Treatment with an IFN in combination with an antiviral agent (Ribavirin), the identity of IFN as recombinant [human] IFN-b or consensus interferon or IFN fused to an immunoglobulin domain, and dosage and routes of administration of IFN and additional antiviral agent (Ribavirin).

State of the prior art: Publication of the discovery of a possible etiological agent of SARS was published in April and May, 2003 following completion

of the work in March, 2003. Although one study concerning the efficacy of IFN treatment of SARS in the PRC was conducted in the spring of 2003 (subsequently published in July), no effective treatment of the viral infection was available at the time the instant Application was filed. Standard of care was palliative and primarily comprised corticosteroid administration.

Experimental animal (human) and in vitro studies with other coronaviruses (notably 229E) demonstrated effectiveness of IFN treatment in mice, humans and in vitro.

Breadth of the claims: The claims somewhat broad; IFN, in general is claimed in the independent claim although the nature of IFN is limited in dependent claims. Likewise, the limitation of co-administration of IFN with an antiviral in claim 15 is subsequently limited to co-administration with Ribavirin.

Working examples: None.

Guidance in the specification: Relatively clear guidance is given for proposed clinical trials especially concerning sample and data collection. However, the identity of IFN, route of administration, dosage, etc. is not provided.

Predictability of the art: The art of antiviral therapy with IFN is highly unpredictable. For example, treatment of HCV infection is highly dependent on the genotype of the virus; combination therapy with pegylated interferon and ribavirin is the treatment of choice resulting in sustained response rates of 40%-80% (up to 50% for patients infected

with the most common genotype found in the U.S. [genotype 1] and up to 80% for patients infected with genotypes 2 or 3).

Amount of experimentation: The type of experimentation regarding IFN and IFN/antiviral treatment of SARS is fairly routine. However, post-filing literature suggests that neither IFN nor IFN/antiviral treatments are effective in the treatment of SARS. Thus, the type and amount of experimentation regarding developing effective IFN therapies now verges on non-routine; similarly, co-administration of an additional, effective antiviral with IFN awaits development of effective anti-SARS-CoV therapeutics.

Given the breadth of the claims, the lack of guidance in the specification, and the predictability of the art, it would require undue experimentation for one skilled in the art to use the claimed composition and method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 14, 17, 18, 25-29 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higgins *et al.* in view of Ksiazek, *et al.*, Arnason and Weinstock-Guttman, *et al.* Claims 14,17, 18, and 25-29 are drawn to a method of treatment of SARS using interferon (IFN), limited in some claims to IFN-β (17) or

"consensus" IFN (18). Claims 25-29 limit the method according to dosage (1-50 μg/day), frequency of administration (daily or every other day), or route of administration (subcutaneously (28) or intramuscularly (29)). Claim 32-33 do not further limit claim 14 because IFN is an antiviral *per se* and the claims do not require an additional antiviral agent.

Higgins *et al.* specifically teach use of purified, recombinant human interferon to prevent or treat the human corona virus, 229E. In the study, volunteers were treated intranasally with interferon or placebo and then inoculated with the virus; the results showed that interferon greatly reduced the infection rate and the severity and duration of cold symptoms; the effective dose was 1.2×10^7 U/day administered daily—1.2×10^7 U is equivalent to 44 μg of IFN. Higgins *et al.* does not specifically teach of using interferon *in vivo* against the related respiratory corona virus, SARS-CoV nor does Higgins, *et al.* teach a route of administration. Ksiazek, *et al.* teaches that a coronavirus, SARS-CoV, is the etiologic agent of SARS. Arnason teaches that IFN-β is effective if administered subcutaneously whilst Weinstock-Guttman, *et al.* teaches that it is also effective if administered intramuscularly. With regard to the limitations "IFN-β or consensus IFN", Applicants' specification defines each to include "analogs", a term that encompass all Type I IFNs and within the teachings of Higgins, *et al*, Arnason, and/or Weinstock-Guttman, *et al.*

The skilled artisan would have been motivated to use interferon preparations in the treatment of SARS because no treatment for SARS was available at the time

and interferon had previously been used to treat another human coronavirus. There would have been a reasonable expectation of success, given that interferon was effective against another coronavirus, as taught by Higgins, *et al.* and the fact that SARS results from a coronavirus infection, as taught by Ksiazek, *et al.* Thus, the invention of claims 14, 17, 18, 25-29 and 32-33 was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

4. Claims 15-16, 19-20,30-31, and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higgins *et al.*, Ksiazek, *et al.*, Arnason and Weinstock-Guttman, *et al.* as applied to claims 14, 17, 18, 25-29 and 32-33 above in further view of Albrecht. Higgins *et al.*, Ksiazek, *et al.*, Arnason and Weinstock-Guttman, *et al.* do not teach combination therapy of IFN and ribavirin, Albrecht does.

The skilled artisan would have been motivated to use interferon in combination with Ribavirin for the treatment of SARS because no treatment for SARS was available at the time and interferon/ribavirin had previously been used to treat another RNA virus. There would have been a reasonable expectation of success, given that interferon/ribavirin combination therapy was effective against another RNA virus, as taught by Albrecht. Thus, the invention of claims 15-16, 19-20,30-31 and 34-36 was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

5. Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higgins *et al.*, Ksiazek, *et al.*, Arnason, Weinstock-Guttman, *et al.*, and Albrecht as applied to claims 14-20 and 25-36 above in further view of Chang, *et al.*

Higgins *et al.*, Ksiazek, *et al.*, Arnason, Weinstock-Guttman, *et al.*, and Albrecht do not teach a chimeric protein comprising IFN and immunoglobulin, Chang, *et al.* does.

The skilled artisan would have been motivated to use interferon/immunoglobulin chimeric protein for the treatment of SARS because no treatment for SARS was available at the time and interferon/IgG had previously been used to treat another virus. There would have been a reasonable expectation of success, given that interferon/immunoglobulin was effective against another virus, as taught by Chang, *et al*; see column 8. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart W. Snyder whose telephone number is (571) 272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stuart W Snyder
Examiner
Art Unit 1648

SWS

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